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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Ralf Ehricht

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EXAMINER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/038,284	EHRICHT ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 17 August 2009 in which claim 66 was amended and the previous rejections were traversed. The amendments have been thoroughly reviewed and entered.

The previous rejection in the Office Action dated 17 April 2009 under 35 U.S.C. 112, second paragraph is withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 103(a) are maintained. Applicant's arguments have been thoroughly reviewed and are discussed below.

Claims 51-67 are under prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 51-55, 58-64, 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrevski et al (U.S. Patent No. 5,882,903, issued 16 March 1999) in view of Stapleton et al (U.S. Patent No. 5,922,604, issued 13 July 1999)

Regarding Claim 51, Andrevski teaches a device for duplicating and characterizing nucleic acids, the device comprising a support (252) having an optically

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permeable surface facing the reaction chamber (Column 11, line 63-Column 12, line 12) and a chamber body sealed onto the chamber support (210 and 216) having a recess having an edge (211) that supports a substrate (251) and an inlet providing fluid communication to the reaction chamber (231) and an optically permeable chip (251, Column 11, line 63-Column 12, line 12) sealed to the supporting edge of the recess (Column 5, lines 3-21) and having a surface facing the reaction chamber wherein the surfaces forming the reaction chamber are parallel (Fig. 2B). Andrevski further teaches the reaction chamber contains nucleic acids for PCR amplification, but does not teach that a surface forming the chamber has an array of immobilized probes.

However, PCR amplification chambers having arrayed probes were well known in the art at the time the instant invention was made as taught by Stapleton.

Stapleton et al teach a similar device for PCR comprising a chamber support having an optically permeable surface (glass slide, 14) a chamber body sealingly placed to form a continuous cavity enclosing the array (Column 5, line 40-Column 6, line 9), wherein the cavity contains an array of nucleic acid probes immobilization (Column 5, lines 40-44). Stapleton further teaches the arrayed probes provides a large surface areas to volume ratio reduces the amount of reagents required while increasing the number of reactions performed and facilitates temperature cycling required for PCR (Column 4, lines 22-36). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the arrayed probes of Stapleton to the PCR chamber of Andrevski. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success for the benefit of reducing reagents

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required while increasing the number of reactions and facilitating temperature cycling required for PCR as desired in the art (Stapleton, Column 4, lines 22-36).

Regarding Claim 52, Andrevski teaches the device further comprises temperature adjustment means (Column 26, lines 8-15 and 34-51). And Stapleton teaches the similar device further comprising a temperature adjustment means connected to the chamber adapted to permit temperature control (e.g. temperature sensor and valves, Column 13, lines 16-25).

Regarding Claim 53, Andrevski teaches similar device wherein the temperature adjustment means are on the sidewalls (end plates) of the chamber (Column 27, lines 20-24). And Stapleton teaches the similar device wherein the temperature adjustment means are on the sidewalls of the chamber (Column 13, lines 57-60).

Regarding Claim 54, Andrevski teaches similar device wherein the temperature adjustment means are on the sidewalls (end plates) of the chamber and therefore does not affect transparently of the substrate (Column 27, lines 20-24). And Stapleton teaches the similar device the detection zone includes detection spots (i.e. probe array) and the temperature adjustment means does not affect the transparency of the chip i.e. on the sidewalls of the chamber (Column 13, lines 57-60 and Column 14, lines 36-57).

Regarding Claim 55, Stapleton teaches the similar device wherein the heating elements comprise micro-structured elements (Column 14, lines 9-17).

Regarding Claim 58, Andrevski teaches the devices wherein the support and body are made of optically permeable material e.g. synthetic (Column 11, line 63-Column 12, line 12 and Column 9, lines 42-50). And Stapleton teaches the similar

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device wherein the chamber support and body consist of optically permeable material e.g. glass (Column 14, lines 40-57).

Regarding Claim 59, Andrevski teaches the device wherein the chamber consists of thermally conducting material (Fig. 6-7). And Stapleton teaches the similar device wherein the chamber support consists of thermally conducting material (Column 13, lines 57-60).

Regarding Claim 60, Andrevski teaches the device wherein the upper and lower covers forming the PCR chamber are optically permeable (Column 11, line 62-Column 12, line 12). And Stapleton teaches the similar device wherein the reaction chamber comprises probes immobilized on a chip consisting of optically permeable material e.g. glass (Column 14, lines 40-57).

Regarding Claim 61, Andrevski teaches the recess formed by sidewalls 211 is aligned with the reaction chamber (Fig. 2B) but does not teach a conical shape.

However, the courts have stated that absent evidence to the contrary, a particular configuration of a known device is a matter of choice which would have been obvious to one skilled in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

Furthermore, Stapleton teaches the similar device further comprising an optically permeable conical recess in the detection area (inverted cone #28, Column 9, lines 50-59).

Regarding Claim 62, Andrevski teaches the device further comprising spatially separate inlet and outlet (231/232, Fig. 2B). And Stapleton teaches the similar device further comprising spatially separate inlet (#20) and outlet (#30).

Regarding Claim 63, Andrevski teaches the device wherein the inlet and outlet are arranged unilaterally and separated by gas inlet/outlet (510A/B, Fig. 7A). Stapleton teaches the similar device wherein the spatially separate inlet (#20) and outlet (#30) are arranged unilaterally to the chip (Fig. 1) and separated by a gas reservoir (i.e. inflatable valve, Column 13, lines 26-40).

Regarding Claim 64, Andrevski teaches the device wherein the cover and bottom plates are joined to form a "fluid-tight seal" (Column 4, lines 47-50) but does not specifically teach an adhesive seal. However, Stapleton teaches the similar device wherein the chamber is sealingly connected to the support by an adhesive (Column 5, lines 45-54).

Regarding Claim 66, Andrevski teaches the reaction chamber is configured for optical detection (Column 12, lines 2-12). And Stapleton teaches the similar device wherein the reaction chamber is configured for optical detection (Column 14, lines 41-43).

Regarding Claim 67, Andrevski teaches the device wherein the precipitating labels are detected (Column 20, lines 35-43) and further teaches the device comprises

upper and lower plates are transparent for signal detection (Column 11, line 63-Column 12, line 12). The instant specification defines a transparent chamber for optical detection (paragraph spanning pages 20-21) but does not define any additional structural requirement for characterization of silver precipitation. Hence, the transparent chamber allowing optical detection as taught by Andrevski is encompassed by the claim.

4. Claims 56 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrevski et al (U.S. Patent No. 5,882,903, issued 16 March 1999) in view of Stapleton et al (U.S. Patent No. 5,922,604, issued 13 July 1999) as applied to Claim 51 above and further in view of McBride et al (U.S. Patent No. 6,296,752, filed 4 June 1999) as defined by Academic Press Dictionary of Science and Technology (Academic Press, San Diego, 1992, page 1768)

Regarding Claims 56 and 57, Andrevski teaches the device comprise beads for mixing the sample (Column 15, lines 19-22). And Stapleton et al teach the device comprising automated fluidic movement (Column 9, lines 9-36 and Column 14, lines 25-35). However, Andrevski and Stapleton are silent regarding a quadrupole system comprising electrodes of gold-titanium.

However, electro-osmotic flow provided by gold-titanium electrodes was well known in the art at the time the claimed invention was made as taught by McBride et al who teach that improved electrodes for providing electro-osmotic flow comprise gold and titanium (Column 4, lines 1-16) wherein their electrode device comprises multiple

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electrodes providing a distribution of magnetic poles (Column 3, lines 34-55).

Furthermore, Academic Press Dictionary of Science and Technology defines a distribution of magnetic poles as a quadrupole. Therefore, the multiple electrode device of McBride et al is a quadrupole system as defined by the Academic Press Dictionary.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the multiple gold-titanium electrodes of McBride et al to the electrodes of Stapleton et al based on the improved teaching of McBride et al (Column 4, lines 1-16).

5. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Andrevski et al (U.S. Patent No. 5,882,903, issued 16 March 1999) in view of Stapleton et al (U.S. Patent No. 5,922,604, issued 13 July 1999) as applied to Claim 51 above and further in view of Fodor et al (U.S. Patent No. 5,744,101, issued 28 April 1998).

Regarding Claim 65, Andrevski does not teach immobilized probes. However, Stapleton teaches the similar device wherein the preferred probe arrays are made using the method of Affymetrix (Column 14, lines 46-49). Stapleton does not specifically teach the probes immobilized through spacers.

However, Fodor et al (i.e. Affymetrix and VLSIPS technology) teach their probes are DNA or RNA (Column 5, lines 32-34) and immobilized through spacers (i.e. linkers) and they teach a motivation to immobilize through spacers i.e. degree of probe-target

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binding is dependent on the presence of spacers (Column 18, lines 42-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the spacers of Fodor et al to the immobilized probes of Stapleton et al to thereby maximize probe-target binding as taught by Fodor et al (Column 18, lines 39-41).

Response to Arguments

6. Applicant asserts that the device of Andrevski requires at least five distinct elements to assemble the reaction chamber, but does not teach a chamber body sealing placed on the chamber support as defined by the instant specification. Applicant points to page 14 of the specification wherein a chamber body is defined as in a rigid, unreleasable connection with the support which can be realized by adhesion, melt connection or manufactured integration. Applicant asserts that the combination of Andrevski and Stapleton fails to teach the sealed arrangement as claimed.

The argument has been considered but is not found persuasive because the open claim language "comprising" of the instant claims encompasses the additional elements in the device of Andrevski. The instant claims do not limit or define the sealed arrangement so as to exclude any additional sealing components. For these reasons, the sealed arrangement of Andrevski is encompassed by the claims.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a rigid, unreleasable connection with the support via adhesion, melt connection or manufactured integration) are not recited in the rejected claims. Although the claims

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are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the passage cited by Applicant defines means by which the sealing "can be realized". Thus the passage merely defines possible sealing arrangements without limiting the claimed invention. For all the above reasons, the arguments are not found persuasive. The rejections are maintained and made FINAL.

Conclusion

7. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BJ Forman
Primary Examiner
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